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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,836	03/04/2005	Kilwon Cho	DE1615	9374
1109 7590 04/02/2007 ANDERSON, KILL & OLICK, P.C. 1251 AVENUE OF THE AMERICAS NEW YORK,, NY 10020-1182			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/02/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/526,836		CHO ET AL.	
	Examiner		Art Unit	
	James W. Rogers, Ph.D.		1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment to the claims and the abstract has been entered.

Examiners observation

The examiner notes that applicants have amended the abstract and claim 1 so that the average number of the functional groups is from 1.1 to 30. While the examiner feels there is sufficient support from page 4 lines 10-26, that the functional groups would have a number average from 1.1 to 30 since the functional group W is connected directly to the hydrophobic block wherein z is the average number of repeating units of the polymer and z is between 1.1 to 30. However the examiner suggests for clarification and to put the claims in better form that applicants should instead of limiting the functional groups to an average number between 1.1 to 30 to recite that the hydrophobic block contains the functional group and has an average number of repeating units of from 1.1 to 30. This is only a suggestion not an objection or rejection and therefore applicants are not required to amend their claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cha et al. (US 5,702,717), for the reasons expressed in the previous office action dated 12/08/2006.

Applicants arguments/remarks made in the amendment filed 03/08/2007 have been fully considered but are not persuasive.

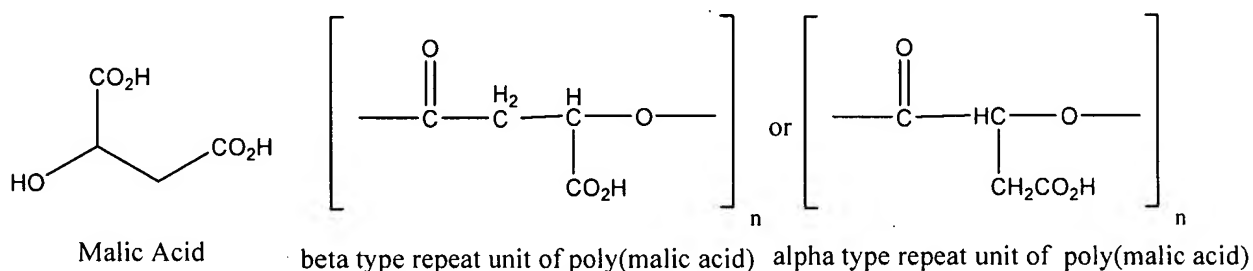
The new rejection of claim 15 was necessitated by amendment for the reasons expressed below and in the previous office action dated 12/08/2006.

Applicants asserts that Cha does not teach a micelle composition for a hydrophobic drug comprising an amphiphilic block copolymer wherein the block copolymer carries hydrogenated functional groups having an average number of 1.1 to 30. Applicants also assert that Cha fails to teach a pharmaceutical composition comprising a hydrophobic drug introduced in the hydrophobic block of the micelle composition. Applicants assert that schemes 1 and 2 within Cha clearly show that malic acid is converted to an ester group and is therefore not a hydrogenated carboxylate group.

The relevance of these assertions is unclear. Clearly Cha teaches that at low concentrations of block copolymer emulsions are formed and both emulsions and gels can be functional in regards to their invention. It is also recited within Cha that PEG was chosen as the hydrophilic component because of its micelle forming properties. Since the claimed amphiphilic copolymer is the same as applicants claimed invention and the concentrations of applicants claimed invention and Cha are within the same range it is inherent that the same amphiphilic copolymer will form the same physical feature (micelle) in an aqueous solution, this is because the same compound will inherently have the same physical properties. Regarding applicants assertion that the drugs of Cha are different, the drugs (taxol) are the same and both are in aqueous solutions with the same amphiphilic copolymer, therefore the interaction between the drug and copolymer will inherently be the same. Cha also recites that the drug is retained

Art Unit: 1618

intimately within the block copolymer. Regarding applicants assertion that Cha does not teach functional groups with an average number between 1.1 and 30, this assertion is very unclear. Schemes 1 and 2 within Cha show 1) a PEG-PLA-PCL block copolymer and 2) a PEG-PCL polymer, neither scheme recites or shows the use of malic acid. To demonstrate why malic acid reads on applicants claimed invention the examiner calls to attention to the scheme below:



Clearly from the above scheme it can be seen that each monomeric unit of malic acid would comprise the hydrogenated carboxylate functional group. As clearly recited in the last office action since Cha teaches that the hydrophobic block can comprise malic acid (functional group is a carboxylate) and the MW range is so broad (preferably 500-3,000) Cha inherently teaches the same amount of functional groups, for instance 25 malic acid units would have a MW ~2900. For further evidence that malic acid forms polymers with the type of repeat units described above the examiner draws the attention of applicants to the teachings of Cammas et al. as evidence (Macromolecules 1993, 4681-4684), the reference clearly shows that poly(malic acid) has a carboxylate functional group.

Claim Rejections - 35 USC § 103

Art Unit: 1618

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al. (US 5,702,717), for the reasons set forth in the previous office action dated 12/08/2006.

The new rejection of claim 15 was necessitated by amendment for the reasons expressed below and in the previous office action dated 12/08/2006.

Applicants assert that as above in the 35 USC 102 arguments above that Cha does not disclose a micelle composition for a hydrophobic drug comprising an amphiphilic block copolymer wherein the block copolymer carries hydrogenated functional groups having an average number of 1.1 to 30. Applicants also assert that

Cha fails to disclose a pharmaceutical composition comprising a hydrophobic drug introduced in the hydrophobic block of the micelle composition. Applicants assert that schemes 1 and 2 within Cha clearly show that malic acid is converted to an ester group.

The remarks above from the examiner in the 35 USC 102 arguments are applied herein as well since the argument by applicants is essentially the same as above.

Applicants further state that the inventive micelle composition shows unexpected effect owing to the features of the block copolymer, applicants state the effect is a higher amount of drug contained within the hydrophobic core.

The relevance of this showing is unclear. Obviously from Cha the skilled artisan could select the same copolymers as applicants claimed aqueous drug containing amphiphilic copolymer composition. Since the composition that could have been selected within Cha is the same composition as applicants it will obviously have the same benefits as applicants claimed invention. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 1-7 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/87345, cited by applicants), for the reasons set forth in the previous office action dated 12/08/2006.

The new rejection of claim 15 was necessitated by amendment for the reasons expressed below and in the previous office action dated 12/08/2006.

Applicants assert that Seo discloses that only one functional group at the end of the block copolymer remains after polymerization to interact with the hydrophobic drug and that further the end group end capped by acylation thereby forming an ester capping which is not a hydrogenated functional group as claimed. Thus applicants state Seo does not disclose an amphiphilic copolymer with a hydrophobic block containing an average of 1.1 to 30 functional groups nor does Seo disclose that the drug is introduced in the hydrophobic block of the micelle.

The relevance of this assertion is unclear.

Firstly as currently amended the claims do not recite that the functional group must be hydrogenated, only that the functional groups are selected from carboxyl, hydroxyl, amine, amide, thiol and sulfonic acid groups, particular attention is drawn to amines and amides, these functional groups do not have to be hydrogenated at all (for instance a tertiary amine with 3 aliphatic groups). Secondly as previously pointed out in the previous office action the aqueous micellular solution of Seo contains an amphiphilic block copolymer comprised of a hydrophilic segment eg PEG and a hydrophobic segment comprised of copolymers of lactide and glycolide **or poly(amino acid)s**. Poly(amino acids) are essentially comprised of repeating peptide bonds or amide bonds, thus meeting the limitation of claim 1. It is also obvious that the 20 naturally occurring amino acids can contain thiol, amine and hydroxyl groups attached to their backbone further meeting applicants claimed invention, as already stated in the

Art Unit: 1618

previous office action. The limitation that the hydrophobic block contains 1-30 functional groups is also met because the MW range of the hydrophobic block within Seo is quite large 1,000-10,000 Daltons, for instance a polylysine hydrophobic segment with 10 monomers would have a MW of ~1300, meeting applicants limitation. Regarding applicants assertion Seo does not disclose a pharmaceutical composition comprising a hydrophobic drug introduced in the hydrophobic block, the drugs (paclitaxol) are the same and both are in aqueous solutions with the same claimed amphiphilic copolymer, therefore the interaction between the drug and copolymer will obviously be the same.

The remarks above on the unexpected results are applied herein as well since the amphiphilic copolymer drug composition of Seo is obviously the same as applicants claimed invention the Seo composition will also have the same benefits.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1618

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).




MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER